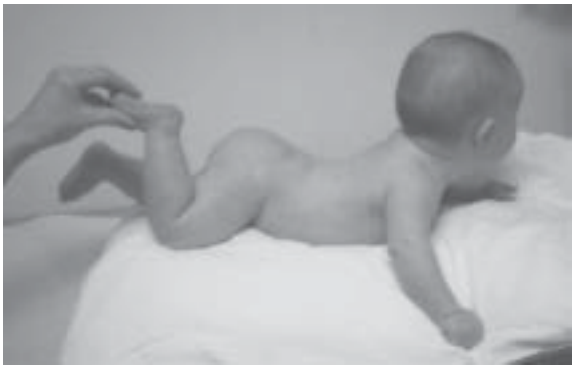
Important Information
for Parents about the

# Newborn Screening Test



California
Department of
Health Services

Newborn Screening Program
Genetic Disease Branch
www.dhs.ca.gov/gdb

# The California Newborn Screening Test

Newborn screening can save your baby's life. Babies can look very healthy at birth and still have a serious disease. If these diseases are not found and treated soon after birth the baby can have serious health problems, or even die. Newborn screening can identify babies with certain diseases so that treatment can be started right away. Early treatment can prevent mental retardation and/or life threatening illness. Make sure your baby is tested.

## What Diseases Are Screened for in California?

California wants to protect the health of all its newborns, so state law requires that, before leaving the hospital, your baby must have the Newborn Screening (NBS) Test for:

- PKU (Phenylketonuria)
- Galactosemia
- Primary Congenital Hypothyroidism
- Sickle Cell Disease and other Hemoglobin Diseases

Every year there are about 450 babies born in California identified with one of these diseases.

## What is Screening?

Screening tests help identify people of any age who seem healthy but who have a disease. Newborn screening identifies most, but not all, of the babies born with the many diseases screened for by the Newborn Screening Program. If you have any questions about your baby's health, ask your baby's doctor. Babies also need regular well-baby care to see how the baby is growing, provide immunizations, and to check for health problems including these diseases.

## Make Sure Your Baby is Tested

Babies with one of these diseases can look very healthy when they are born. By the time symptoms appear, it may be too late to prevent serious damage to the baby. That is why your baby will be tested before leaving the hospital.

## Can These Diseases Be Treated?

Effective treatment is available for all of the diseases listed. Early identification and treatment of these diseases can prevent mental retardation and/or life-threatening illness. Treatment may include special diets or drugs. Babies who receive early and ongoing treatment can grow up to enjoy long, productive lives.

## When Should The Test Be Done?

The newborn screening test should be done when babies are between 12 hours and 6 days of age. When the blood is collected before 12 hours of age, the test for PKU is not always accurate so another blood sample must be taken later to repeat the test. If you leave the hospital or birthing center with your baby before he/she is 12 hours old, you will have to return within the next few days for another test.

Babies not born in the hospital must also have this test. It should be done before your baby is six days old. Call your midwife, the baby's doctor or your local health department to have your baby tested.

## Is The Test Safe?

Yes, millions of newborns have been tested without any harm to the newborn. A few drops of blood will be taken from your baby's heel. This is a simple and safe test. The blood will be sent to a State-approved lab for testing.

## Can I Say No To The Test?

You can only say no for specific religious reasons. If you say "no" you must sign a special form. It says your hospital, doctor and the clinic staff are not responsible if your baby develops problems because these diseases were not identified and treated early.

## Is The Test Accurate?

Yes, the laboratory test is accurate and the State monitors the performance of the testing laboratories closely to make sure the results are reliable. Only rarely is a baby with one of these diseases not found through the newborn screening test. However, some newborns without any of these diseases will also be positive in order to detect as many cases as possible.

## How Can I Get The Results?

You can get your baby's test results from your doctor or clinic. It takes about two weeks for doctors to receive negative test results. If your doctor does not have the results, he or she can contact the newborn screening program to request a copy.

If you move after the test is done, make sure the hospital, and your baby's doctor or clinic has your new address and phone number in case they need to contact you about your baby's results.

## What Do I Do If The Results Are Positive?

If your baby's results are positive more tests will be needed. You should receive a phone call and/or letter with instructions about what to do next. Many babies who have a positive first test, after further testing are found NOT to have a disorder. However, it is important to have your baby re-tested because babies who do have one of these diseases benefit from early treatment.

## Early Treatment Can Prevent Serious Problems

These diseases can cause serious health problems. Early treatment can prevent many of these problems.

- ***PKU (Phenylketonuria)***

Babies born with PKU have problems when they eat foods high in protein such as milk, including breast milk and formula, meat, eggs and cheese. Without treatment babies with PKU become mentally retarded and/or have other health problems. A special diet can help prevent these problems.

- ***Galactosemia***

Babies with this disease cannot use some of the sugars in milk, formula and breast milk, and other foods. This disorder harms the baby's eyes, liver and brain. Without treatment, babies with galactosemia can become very sick and die. A special infant formula and diet can help prevent these problems.

- ***Primary Congenital Hypothyroidism***

Babies born with this disease lack a thyroid hormone. Without this hormone they grow very slowly and become mentally retarded. These problems can be prevented by giving the baby special medicine every day.

- ***Sickle Cell Disease and other Hemoglobin Diseases***

These diseases affect the baby's red blood cells. Babies with sickle cell disease can get very sick and even die from common infections. Many of the infections can be prevented with daily antibiotics. Babies with other hemoglobin diseases may need blood transfusions. Ongoing health care and close monitoring help children with hemoglobin diseases stay as healthy as possible.

## How Much Does The Test Cost?

The fee is subject to change. Please check with your doctor or hospital for the current cost of the test. Medi-Cal, health plans and most private insurance will pay for the test. The cost is included in the hospital bill. If you have problems with your insurance, contact 1-800-927-HELP or if you have a prepaid health plan, contact 1-888-HMO-2219.

## Is the information about my baby's test confidential?

Yes. For details of our privacy protection policies, read the detailed notice included on pages 7-8.

## Optional Supplemental Screening

The Newborn Screening Program screens for the most common treatable diseases. We are always evaluating new diseases as testing techniques and treatments become available. However, there is a period of time between the availability of a test technique and it being included in the statewide program.

Parents should be aware that tests for other conditions are available from private laboratories for a fee. Some of these conditions are common enough and have effective treatment options to ultimately justify their inclusion in the State program. These include Congenital Adrenal Hyperplasia, Biotinidase Deficiency, Medium Chain Acyl CoA Dehydrogenase Deficiency (MCADD), and some other diseases detected by tandem mass spectrometry technology.

Parents should discuss supplemental testing with their prenatal and/or pediatric physicians who can arrange for testing by a private laboratory. The Newborn Screening Program will not pay for the supplemental screening.

Information on these diseases is available also at these websites:

CARES: www.caresfoundation.org
Alliance for Genetic Disorders: www.geneticalliance.org
Star G Project: www.newbornscreening.info

Information on tests and costs can be also obtained by contacting the following laboratories directly:

**Baylor**: 1-800-4BAYLOR
www.bhcs.com/MedicalSpecialties/MetabolicDisease

**Mayo**: 1-800-533-1710
www.mayoreferenceservices.org/mml/mml-sns-intro.asp

**Pediatrix**: 1-866-463-6436
www.pediatrixscreening.com

## *Questions for My Doctor*

The Genetic Disease Branch wants to provide quality services to the families of California and welcomes your comments and suggestions.

**NOTICE OF INFORMATION PRACTICES AND PRIVACY PRACTICES**
**CALIFORNIA DEPARTMENT OF HEALTH SERVICES**
**GENETIC DISEASE BRANCH NEWBORN SCREENING PROGRAM**
**EFFECTIVE DATE APRIL 14, 2003**

**This Notice Describes How Personal (Including Medical) Information About You Or Your Newborn May Be Used And Disclosed And How You Can Get Access To This Information. Please Review It Carefully.**

**Department's Legal Duty.** Federal and State laws restrict the use, maintenance and disclosure of personal (including medical) information obtained by a State agency, and require certain notices to individuals whose information is maintained. State laws include the California Information Practices Act (Civil Code 1798 et. seq.), Government Code Section 11015.5 and Health and Safety Code Section 124980. The federal law is the Health Insurance Portability and Accountability Act of 1996 (HIPAA) 42 USC 1320d-2(a)(2), and its regulations in Title 45 Code of Federal Regulations Section 160.100 et. seq. In compliance with these laws, you and those providing information are notified of the following:

**Department Authority and Purpose for the Newborn Screening Program.** The Department of Health Services is authorized to collect information related to newborn screening in Health and Safety Code Sections 124980, 125000, 125001, 125025, and 125030. This information is collected electronically and includes such things as your name, address, medical care given to you and your newborn. This information is used to identify newborns with inherited or congenital disorders in order to prevent or provide treatment for the disorder. Testing is required by law (Health and Safety Code Section 125000) and regulations (17 CCR 6500 through 6510) and if the required information is not provided, the death or permanent handicaps for affected newborns could result. If you have religious objections to testing, you may say "no" to testing in writing and you will sign a form advising you that your hospital, doctor and clinic staff are not responsible if your baby develops problems because those disorders were not identified and treated early.

**Uses and Disclosure of Health Information.** The Department of Health Services uses health information about you or your newborn for screening, to provide health care services, to obtain payment for screening, for administrative purposes, and to evaluate the quality of care that you or your newborn receive. Some of this information is retained for as long as 21 years. The information will not be sold.

The law also allows the Department to use or give out information we have about you or your newborns for the following reasons:

- For research studies that have been approved by an institutional review board and meet all federal and state privacy law requirements, such as research related to preventing disease.
- For medical research without identification of the person from whom the information was obtained, unless you specifically request in writing that your information not be used by contacting the person listed below.
- To organizations, which help us in our operations, such as by collecting fees. If we do, we will make sure that they protect the privacy of information we share with them as required by federal and state law.

The information is otherwise confidential and will not be released without your written authorization. If you choose to sign an authorization to disclose information you can later revoke that authorization to stop any future uses and disclosures by contacting the person listed below.

The Department may change its policies at any time subject to applicable laws and regulations. If it does so, we will notify you and you may request a copy of our current policies or obtain more information about our privacy practices, by contacting the person listed below or consulting our website at www.dhs.ca.gov/pcfh/gdb. You may also request a paper copy of this Notice.

**Individual Rights and Access to Information**. You have the right to look at or receive a copy of your or your newborn's health information. If you request copies, we will charge you $0.10 (10 cents) for each page. You also have the right to receive a list of instances where we have disclosed health information about you or your newborn for reasons other than screening, payment or related administrative purposes. If you believe that information in your or your newborn's record is incorrect or if important information is missing, you have the right to request that we correct the existing information or add the missing information. You have the right to ask us to contact you at a different address, post office or telephone number. We will accept reasonable requests.

You may request in writing that we restrict disclosure of your or your newborn's information for health care treatment, payment and administrative purposes. We may not be able to agree to your request.

**Complaints.** If you believe that we have not protected your or your newborn's privacy or have violated any of your or your newborn's rights and wish to complain, please call or write us at: **Privacy Officer,** CA Department of Health Services, P.O. Box 942732, Sacramento, CA 94234-7320, (916) 255-5259 or (877) 735-2929 TTY.

You may file a complaint by calling or writing the **Privacy Officer**, CA Department of Health Services, at the address and telephone number above. You may also contact the Secretary of the Department of Health and Human Services, Office for Civil Rights at 50 United Nations Plaza, Room 322, San Francisco, CA, 94102, telephone (800) 368-1019. Or you may call the U.S. Office of Civil Rights at 1-866-OCR-PRIV (866-627-7748) or 1-866-788-4989 TTY.

**The Department cannot take away your health care benefits or do anything to hurt you in any way if you choose to file a complaint or use any of the privacy rights in this Notice.**

**Department Contact – Who Maintains the Information**. The information on this form is maintained by the Department of Health Services, Genetic Disease Branch. The Chief of the Genetic Disease Branch is George Cunningham, M.D., 850 Marina Bay Parkway, Richmond, California, 94804 (510) 412-1499. He is responsible for the system of records and shall, upon request, inform you about the location of your records and respond to any requests you may have about information in those records.

## AMERICANS WITH DISABILITIES ACT
## Notice and Information Access Statement

Policy of Nondiscrimination on the Basis of Disability and
Equal Employment Opportunity Statement

The Department of Health Services, State of California does not discriminate on the basis of disability in employment or in the admission and access to its programs or activities.

The Deputy Director, Office of Civil Rights, 714 P Street, Room 1050, Sacramento, CA 95814 has been designated to coordinate and carry out the agency's compliance with the nondiscrimination requirements of Title II of the Americans with Disabilities Act (ADA). Information concerning the provisions of the ADA, and the rights provided thereunder, are available from the ADA Coordinator.





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